JUL 17 2014

SHILLA™ Growth Guidance System
510(k) Summary
K140750

July 2014

Company:	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact:	Lee Grant Distinguished Regulatory Affairs Advisor

Proprietary Trade Name:	SHILLA™ Growth Guidance System
Product Code:	PGM
Regulation:	Pre-Amendment Unclassified
Classification:	Unclassified

Description: The SHILLA™ Growth Guidance System is intended to treat severe, progressive multi-planar spinal deformities such as early-onset scoliosis while allowing for skeletal growth. Severe, progressive early-onset scoliosis is defined as a greater than 40° Cobb angle or a rib-vertebral angle difference greater than 20°. The SHILLA™ Growth Guidance System consists of a variety of shapes and sizes of steel rods, hooks, screws, CROSSLINK® Plates, and connecting components, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. All SHILLA™ components are manufactured from medical grade stainless steel.

Indications for Use: The SHILLA™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth, who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome. The SHILLA™ Growth Guidance System is intended to be removed after skeletal maturity.

Summary of the Technological Characteristics: The subject SHILLA™ Growth Guidance System has the same fundamental scientific technology as the predicate CD HORZION® Growth Rod Conversion Set. The subject device utilizes equivalent surgical approaches, implant materials, surgical instruments, and sterilization methods.

Identification of Legally Marketed Devices: The subject SHILLA™ Growth Guidance System is substantially equivalent to the CD HORIZON® Growth Rod Conversion Set K133904 (1/30/14) and to the pre-amendment Harrington Rod Spinal System.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing: Retrospective clinical data for the subject device compared to traditional growth rod devices were provided in support of this application. The clinical outcomes demonstrated the subject SHILLA™ Growth Guidance System to be substantially equivalent to traditional growth rod systems when treating the same patient population. Additionally, mechanical testing was provided which demonstrated the SHILLA™ Growth Guidance System to be substantially equivalent with regards to mechanical strength to the CD HORIZON® Growth Rod Conversion Set.

Conclusion: The design features, materials used, manufacturing and sterilization methods are substantially equivalent to the previously cleared CD HORIZON® Growth Rod Conversion Set. The retrospective clinical data supplied in this application identified no new potential risks to patients and demonstrated substantially equivalent outcomes when comparing the SHILLA™ Growth Guidance System to traditional growth rods. Therefore, Medtronic believes the subject SHILLA™ Growth Guidance System implants contained in this application to be substantially equivalent to the legally marketed predicate CD HORIZON® Growth Rod Conversion Set implants cleared in K133904.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 17, 2014

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K140750
Trade/Device Name: SHILLA™ Growth Guidance System
Regulatory Class: Unclassified
Product Code: PGM
Dated: June 17, 2014
Received: June 19, 2014

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140750

Device Name
SHILLA™ Growth Guidance System

Indications for Use *(Describe)*
The SHILLA™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth, who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome. The SHILLA™ Growth Guidance System is intended to be removed after skeletal maturity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ronald P. Jean -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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